

Application Serial No. 09/960,463
Amendment dated September 7, 2004
Reply to Office Action mailed May 7, 2004

REMARKS/ARGUMENTS

The above-identified patent application has been reviewed in light of the Examiner's Action mailed May 7, 2004 (Paper No. 12). As set forth more fully below, reconsideration and withdrawal of the Examiner's rejections of the claim are respectfully requested.

Claim Rejections Under 35 U.S.C. § 103

The Examiner has rejected Claim 1 under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 6,192,891 (hereinafter "Gravel") in view of U.S. Patent No. 5,281,395 (hereinafter "Markart") and U.S. Patent Application Serial No. 10/180,732 (hereinafter "Malave"). The system taught by Gravel provides both a blood glucose monitor with a display unit and a separate display unit. By contrast, the system of the present invention includes only one display unit that simultaneously displays both the quantity of insulin dispensed and the variation in the measured blood sugar level. This data is displayed by the display unit in the form of a graph showing the quantity of insulin dispensed and the resulting variation in the blood sugar level from a reference value as a function of time as shown in Figure 29 and described at page 38, line 20 through page 39, line 22 of the instant disclosure. This is a particularly advantageous display as the doctor or user can conveniently determine an appropriate quantity of insulin to be dispensed to the user by simply comparing the data displayed on the display unit, without separately measuring the insulin quantity and blood sugar level. Applicant has amended Claim 1 to more clearly recite the way in which the control unit receives and sends this information to the single display unit to be displayed in graphical form. Neither the disclosures of Gravel nor Markart teach or suggest such an interaction with the control unit nor the display of all of this information in graphical form allowing for such easy interpretation of the blood sugar-insulin dose data.

The Examiner also cites Malave as teaching a glucose and infusion pump system including an interface with a processing device that has a display for displaying daily and weekly summaries of the insulin administration record and blood glucose value. This separate display and the computer interface needed to connect and display the data accumulated in the pump

device is in sharp contrast to the pump and integral display of both Gravel and the present invention.

As noted above, Gravel teaches both a display unit and a separate display unit while Malave teaches a separate display unit accessed through an interface. The separate display of Malave displays the blood glucose and insulin dosage history of any day in the preceding weeks of the insulin user's history. However, there is no disclosure or suggestions of how a skilled artisan may combine the historical display of Malave with the two separate displays of Gravel to produce the single display having real time blood glucose monitoring to allow the doctor or user to conveniently determine the appropriate quantity of insulin to be dispensed to the user by simply comparing the data displayed on the single display unit that constitutes a permanent part of the portable insulin syringe device of the present invention.

The device of Malave would need to be configured to provide a display of blood glucose and insulin use in real time which would require permanent attachment to the processing device and elimination of, or permanent connection to, the interface and communication station thereby eliminating the portability of the medical device. Alternatively, the device of Gravel would need to be reconfigured to eliminate one display in favor of a larger display, processing unit, communication station and permanent interface to the communication station. "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). Neither the disclosure of Gravel nor the disclosure of Malave suggest a redesign of the disclosed devices to remove their intended purpose of portability while allowing a historical display through an interface and communication station thereby rendering those devices unsatisfactory for their intended purposes. Thus, Applicant submits that there is no teaching in either Gravel or Malave as to a practical or useful means of combining the devices of Gravel and Malave to form the portable insulin pump device having a single portable display capable of displaying real time insulin and blood glucose monitoring as presently claimed.

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Therefore, Applicant submits that the skilled artisan would have no expectation of successfully combining the devices of Gravel and Malave to form the currently claimed insulin pump device and respectfully request that the Examiner's rejection under 35 U.S.C. § 103 be withdrawn.

Based upon the foregoing, Applicants believe that the pending claim is in condition for allowance and such disposition is respectfully requested. In the event that a telephone conversation would further prosecution and/or expedite allowance, the Examiner is invited to contact the undersigned.

Respectfully submitted,

SHERIDAN ROSS P.C.

By: Robert D. Traver
Robert D. Traver
Registration No. 47,999
1560 Broadway, Suite 1200
Denver, Colorado 80202-5141
(303) 863-9700

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